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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,499	12/19/2005	Toshihiro Shirouzu	KUZ00027US.NP	9337
7590 Licata & Tyrrell 66 East Main Street Marlton, NJ 08053	08/27/2007		EXAMINER HUYNH, CARLIC K	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 08/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/561,499	SHIROUZU ET AL.
	<b>Examiner</b> Carlic K. Huynh	<b>Art Unit</b> 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-13 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) 1-13 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____.	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: ____.

## DETAILED ACTION

### *Election/Restrictions*

1. An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature,” should be considered with respect to novelty and inventive step.

The common technical feature in all groups is an external preparation comprising an anti-trichophyton drug mixed with at least one of 1-methol, a methol analogue, or a bactericidal compound. The element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Takuzo et al. (JP 08-020527 as cited in the IDS) disclose the antimycotic agent, butenafine hydrochloride, with menthol (abstract).

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (1) an anti-trichophyton;
- (2) 1-menthol or a menthol analogue;
- (3) a menthol analogue compound;
- (4) a bactericidal compound;
- (5) a local anesthetic;
- (6) an antihistamine; and
- (7) an anti-inflammatory drug.

Applicant is required, in reply to this action, to elect a single species of (1) an anti-trichophyton, (2) 1-menthol or a menthol analogue compound, (4) a bactericidal compound, (5) a local anesthetic, (6) an antihistamine, and (7) an anti-inflammatory drug to which the claims shall be restricted if no generic claim is finally held to be allowable. If a menthol analogue compound is elected, the applicant is further required, in reply to this action, to elect a single **specific** species of (3) a menthol analogue compound to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species listed above in the following manner:

(1) Claims 1-2, 5-8, and 13 are directed to various anti-trichophyton drugs; (2) Claims 1-2, 7-8, and 13 are directed to either 1-menthol or menthol analogue compound; (3) Claims 1-3 and 8 are directed to various menthol analogue compounds; (4) Claims 1-2, 4, and 8 are directed to various bactericidal compounds; (5) Claims 9-10 and 13 are directed to various local anesthetics; (6) Claims 9-11 and 13 are directed to various antihistamines; and (7) Claims 9-10 and 12-13 are directed to various anti-inflammatory drugs.

The following claim(s) are generic: (1) 1-2, 5-8, and 13; (2) 1-2, 7-8, and 13; (3) 1-3 and 8; (4) 1-2, 4, and 8; (5) 9-10 and 13; (6) 9-11 and 13; and (7) 9-10 and 12-13.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: (1) Claims 1-2, 5-8, and 13 are directed to various anti-trichophyton drugs, of which each anti-trichophyton drug is structurally distinct; (2) Claims 1-2, 7-8, and 13 are directed to either 1-menthol or menthol analogue compound, of which 1-menthol or each menthol analogue compound is structurally distinct; (3) Claims 1-3 and 8 are directed to various menthol analogue compounds, of which each menthol analogue compound is structurally distinct; (4) Claims 1-2, 4, and 8 are directed to various bactericidal compounds, of

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which each bactericidal compound is structurally distinct; (5) Claims 9-10 and 13 are directed to various local anesthetics, of which each local anesthetic is structurally distinct; (6) Claims 9-11 and 13 are directed to various antihistamines, of which each antihistamine is structurally distinct; and (7) Claims 9-10 and 12-13 are directed to various anti-inflammatory drugs, of which each anti-inflammatory drug is structurally distinct.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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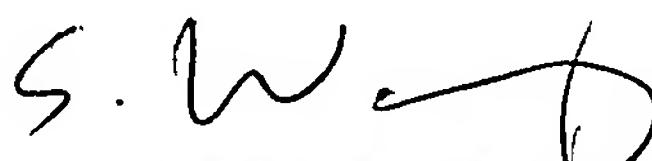
application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



SHENGJUN WANG  
PRIMARY EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh